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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,463	12/03/2003	Bernard Robert Terry	3759-0131P	3697

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,463

Applicant(s)

TERRY ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-21 are pending in the application. Claims 1-21 are under examination.

Priority

2. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications and the current status thereof. In this case, the current status of ASN 09/227,518 is US Patent Number 6,790,652.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite, and incomplete in reciting, "reading the response plate" because it is unclear what interactive process takes place between the array of

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test compounds or control compounds and the detector layer so as to require a response that is detected and read on a plate, since there does not appear to be any reagent, binding partner, or physiologically viable cells with which the test compounds interact to produce the detectable response.

Claim 1, preamble, is vague and indefinite in reciting, "recognizable responses" because the term "recognizable" is a subjective term that lacks a comparative basis for defining its metes and bounds. See also claims 2, 3, and 4.

Claim 1, step b) lacks antecedent basis in reciting, "the response plate".

Claim 1, step c) lacks antecedent basis in reciting, "the true coordinates" and "these known compounds". Are the "known compounds" the same as the "regular control compounds" recited in the preamble of the claim.

The phrase "more than 3" in claim 4 is a relative term which renders the claim indefinite. The term "more than 3" is not defined by the claim, i.e. does not define an upper limit for the response, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 5 is confusing in relation to claim 1 in reciting, "the solid support is a porous membrane" because claim 1 recites "a solid support" and "a membrane" in step a); hence, it is unclear how the elements in claim 1 provide proper antecedent basis for each of the recitations of "the solid support" and "a porous membrane."

Claim 5 lacks antecedent basis in reciting, "the liquid layer". Is the liquid layer the same as the buffer medium upon which the monolayer cells are overlain.

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Claim 6 is vague and indefinite in reciting, “[the test compounds are held on] a non-porous substrate” because it is unclear as to whether the “non-porous substrate” is the same as “[test compounds held on] a solid support” recited in claim 1 from which it depends. Perhaps Applicant intends, “wherein the solid support is a non-porous substrate”.

Claim 10 is vague and indefinite in reciting, “the detector layer is scintillant plastic” because it is unclear what interactive process takes place in claim 1 which requires a response that is to be detected in the detector layer which is scintillant plastic. Specifically, claim 1 only recites, “contacting the array of test compounds ... with the detector layer” which in the instant claim “is scintillant plastic”. It appears that there should be reagent or binding partner or physiologically viable cells with which the test compounds interact and which further comprises the scintillant plastic, to produce a specific response that is measured in the response plate.

Claim 11 is vague and indefinite in reciting, “the detector layer is a pH sensing surface” because it is unclear what interactive process takes place in claim 1 which requires a response that is to be detected in the detector layer which is a pH sensing surface. Specifically, claim 1 only recites, “contacting the array of test compounds ... with the detector layer” which in the instant claim “is a pH sensing surface”. It appears that there should be reagent or binding partner or physiologically viable cells with which the test compounds interact and which further comprises the pH sensing surface, to produce a specific response that is measured in the response plate.

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Claim 12 is vague and indefinite in reciting, "the detector layer is a temperature sensing surface" because it is unclear what interactive process takes place in claim 1 which requires a response that is to be detected in the detector layer which is a temperature sensing surface. Specifically, claim 1 only recites, "contacting the array of test compounds ... with the detector layer" which in the instant claim "is a temperature sensing surface". It appears that there should be reagent or binding partner or physiologically viable cells with which the test compounds interact and which further comprises the temperature sensing surface, to produce a specific response that is measured in the response plate.

Claim 13 is vague and indefinite in reciting, "the detector layer is an optically clear substrate" because it is unclear what interactive process takes place in claim 1 which requires a response that is to be detected in the detector layer which is an optically clear substrate. Specifically, claim 1 only recites, "contacting the array of test compounds ... with the detector layer" which in the instant claim "is an optically clear substrate". It appears that there should be reagent or binding partner or physiologically viable cells with which the test compounds interact and which further comprises the optically clear substrate, to produce a specific response that is measured in the response plate.

Claim 16 lacks antecedent basis in reciting, "the detected response".

Claim 17 lacks antecedent basis in reciting, "the detected response".

Claim 18 lacks antecedent basis in reciting, "the detected response".

Claim 16 lacks antecedent basis in reciting, "the response".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 5-7, 10, and 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Chelsky et al. (US 5,856,083).

Chelsky et al. disclose a lawn assay for screening and determining test compounds that bind to target molecules (see Abstract and column 6, lines 24-36). The test compounds to be screened are arranged in an array and linked on a solid support, i.e. rigid template, and are diffused from the solid support through porous membrane (colloidal matrix) into a detector layer. The detector layer comprises physiologically viable cells having membrane-bound receptors, i.e. target molecules or cell surface antigens, upon which the test compounds react, and are disposed into the porous membrane. The test compounds linked may also be embedded in a porous membrane (see column 3, lines 30-67 and column 6, lines 4-11). Specifically, Chelsky et al. disclose contacting the solid support with the porous membrane so as to cause the test compounds to react with specific cell membrane receptors in the detector layer to determine their effect on bioactivity or inhibition. Active compounds that provide a

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detectable response are located, quantitated, and then identified by reading or viewing the response zones in the membrane for a change in fluorescence and then correlating their position in the template (see column 3, lines 2-9, column 5, and column 7, lines 18-34). Chelsky et al. exemplify incorporating two known control compounds, having known responses, i.e. inhibitors, in the assay method (see column 12). The responses are recorded by sequence of images obtained by photography or video imaging (see column 9, lines 46-49). The array of compounds can be arranged in such a way that the position of the compound in the array corresponds to the identity of the compound. Compound identity may also be determined by chemical tagging; chemical tags encode the identity of the compound and the pattern of the tag is correlated with the identity of the compound (see column 7, lines 36-55). The cells may also be coated upon scintillant plastic plate (see column 3, lines 30-67). Change in fluorescence may be detected using field format fluorescence detection systems capable of exciting the detector layer with any number of selected wavelengths (see column 4, lines 51-64). Other detectable response includes change in chemiluminescence property (see column 5, lines 15-20). The test compounds are generated into solid support using combinatorial chemistry or by electrophoretic procedure (see column 8, lines 5-18 and column 9, lines 20-41). Accordingly, claims 1, 5-7, 10, and 14-21 are anticipated by Chelsky et al.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chelsky et al. (US 5,856,083).

Chelsky et al. has been discussed supra. Chelsky et al. differ from the instant invention in failing to teach using at least three or more control compounds that give known "recognizable" responses.

It is, however, maintained that the number of control compounds used, i.e., three, at least three, or more than three, recited in claims 2, 3, and 4, respectively, are all result effective variables which the prior art reference has shown may be altered in order to achieve optimum results. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges

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by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 2-4 are for any particular purpose or solve any stated problem, and Chelsky teaches that numbers of test compounds or control compounds used in the array method often vary according to the size of the libraries, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures.

6. Claims 8, 9, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chelsky et al. (US 5,856,083) in view of Sittampalam et al. (Current Opinion in Chemical Biology, 1997).

Chelsky et al. has been discussed supra. Chelsky et al. differ from the instant invention in failing to teach that the physiologically viable cells are cultured on a detector layer which is optically clear substrate. Chelsky et al. further differ from the instant invention in failing to teach that the detector layer is a pH sensing device or a temperature sensing device.

Sittampalam et al. teach cell based assay systems for use in high throughput screens wherein physiologically viable cells are cultured, coated (layered), and grown onto a scintillant plastic (detector layer supported by optically clear substrate or plastic

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having scintillating microplates disposed thereto), on the bottom of a microwell plate so that upon contact with a test compound, the cells are monitored for bioactivity (cellular events, cytosolic calcium mobilization) (see page 384, column 1 and page 386, columns 1 and 2). Sittampalam et al. teach applications of pH sensing surface and temperature sensing surface in high-throughput screening devices to detect cellular bioactivity responsive to interaction with different compounds (see page 386-388).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate teachings of Sittampalam in cellular cultures as target molecules for detection of cellular bioactivity using sensing devices, into the high-throughput screening assay method taught by Chelsky because Sittampalam specifically taught and suggested application of the method in high-throughput screening assays and Chelsky further provides advantage and ease in simplifying the handling of high-throughput arrays of multiple compounds incorporated into solid supports, from steps such as weighing, transferring, and distributing individual test compounds, thereby acquiring rapid, even larger scale screening capability in high throughput screening methods (see column 1, Chelsky et al.).

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571)

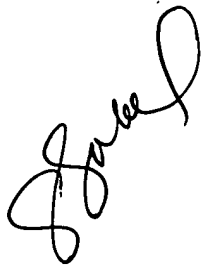
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272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
September 28, 2006

A handwritten signature in black ink, appearing to read 'Gabel', is written over the printed name and date.